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EXAMINER
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THOMAS W. GERARDI

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DATE MAILED: 03 24 2003

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Please find below and or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/779,427

Applicant(s)

STEINBUCHER ET AL.

Examiner

Gerald G Leffers Jr.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/809,286.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

☐ The translation of the foreign language provisional application has been received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt is acknowledged of a new Power of Attorney, filed on 12/30/02 as Paper No. 8, with attached copies of the assignment papers. Receipt is also acknowledged of an amendment, filed 12/30/02 as Paper No. 12, in which several claims were amended (claims 1-18) and in which several new claims were added (proposed claims 37-42). However, because the next available claim number was claim 31, the newly submitted claims have been renumbered as claims 31-36 (Rule 1.126).

Any rejection of record that is not addressed by this action is hereby withdrawn. Claims 1-18 and 31-36 are pending in the instant application. This action is not final because of new grounds of rejection that are raised in the instant action that were not necessitated by applicants' amendment of the claims.

### ***Oath/Declaration***

The supplemental Declaration filed on 12/30/02 for Mathias Leibergessell is proper and obviates the objection made in the previous office action.

### ***Claim Objections***

Claim 3 is objected to because of the following informalities: the presence of the word "and" in the middle of the Markush group between the words "citric acid esters" and "citric acid lactones" is confusing and improper. It would be remedial to amend the claim by deleting "and" at this position and inserting a comma in its place. Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 31-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 comprises the limitation that a "recombinant organism" is used in the methods for producing poly(hydroxy fatty acids). The originally filed specification only describes the use of recombinant bacteria in the claimed methods and does not provide support for the broadly claimed scope of a "recombinant organism" (e.g. a transgenic mouse). Therefore, the newly added limitation of a "recombinant organism" is impermissible NEW MATTER. It would be remedial to amend claim 1 and dependent claims to read on recombinant bacteria, for which there is ample support in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Many of the following rejections are for lack of proper antecedent basis in the claims.

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"incubating" and "cultivation" in the rejected claims, making it unclear whether additional steps are required to practice the claimed method. The specific rejections follow.

Claims 2, 5-7, 11-18, 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "bacteria" in claim 1, upon which claim 2 is directly dependent.

Claim 5 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "poly(hydroxy fatty acids)" in claim 1, upon which claim 6 is directly dependent. Claim 1 recites in the preamble "poly(hydroxy fatty acids)" and further recites "a poly(hydroxy fatty acid)". It would be remedial to amend claim 1 to provide a clear and positive prior antecedent basis for the term "poly(hydroxy fatty acids)".

Claim 6 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "poly(hydroxy fatty acid)" in claim 1, upon which claim 5 is directly dependent. Claim 1 recites in the preamble "poly(hydroxy fatty acids)" and further recites "a poly(hydroxy fatty acid)". It would be remedial to amend claim 1 to provide a clear and positive prior antecedent basis for the term "poly(hydroxy fatty acid)".

Claim 7 is vague and indefinite in that the metes and bounds of the phrase "cultivated at cell densities of up to 100 g of dry cellular mass per liter of bacterial nutrient medium" are unclear. It is unclear whether the step of "cultivation" implies an additional step to the

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clear and positive prior antecedent basis for the term "recombinant bacteria" in claim 1, upon which claim 7 is directly dependent.

Claim 11 is vague and indefinite in that the metes and bounds of the phrase "after approximately 12 h and 24 h at approximately 27°C to 35°C" are unclear. It is unclear as the claim is written as to whether the phrase "27°C to 35°C" simply refers to the temperature at the time of addition of the carbon source to the culture media, or refers to the temperature of the culture media for the duration of the incubation or cultivation time. It would be remedial to amend the claim by making clear what exactly is referred to by the duration and temperature limitations recited in the claim (e.g. by spelling out "hours" and by inserting the appropriate term, incubation or cultivation or growth, etc.).

Claim 12 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "cultivation" in claim 1, upon which claim 12 is directly dependent. It is unclear whether the step of "cultivation" implies an additional step to the "incubation" step of claim 1, or whether it specifies an additional method step.

Claim 13 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "recombinant bacteria" in claim 1, upon which claim 13 is directly dependent.

Claims 14-15 are vague and indefinite in that there is no clear and positive prior antecedent basis for the term "harvested recombinant bacteria" in claim 1, upon which these claims are directly dependent. These claims are further vague and indefinite in that there is no clear and positive prior antecedent basis for the term "poly(hydroxy fatty acids)" in claim 1, upon which these claims are dependent.

Claim 16 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "poly(hydroxy fatty acid)" in claim 1, upon which claim 16 is indirectly dependent. Claim 1 recites in the preamble "poly(hydroxy fatty acids)" and further recites "a poly(hydroxy fatty acid)". It would be remedial to amend claim 1 to provide a clear and positive prior antecedent basis for the term "poly(hydroxy fatty acid)".

Claim 16 is further vague and indefinite in that the metes and bounds of the phrase "wherein the product is obtained essentially pure form by removing the hydrophilic solvent" are unclear. The term "essentially pure" is not explicitly defined in the specification and is subjective. It is not clear that the term "essentially pure" does not add a further limitation to the step of obtaining the product by removing the hydrophilic solvent after precipitation of the product. If it is meant to add a further limitation to the step of removing the hydrophilic solvent, the intended limitation needs to be set forth such that one can understand its metes and bounds. If the term "essentially pure" simply describes the state of the product following removal of the hydrophilic solvent, the term is unnecessarily confusing and should be deleted from the claim.

Claim 17 is vague and indefinite in that there is no clear and positive prior antecedent basis for the terms "harvested recombinant bacteria" and "the bio-reactor". Also, the phrase "in order to be processed further" implies some further limitation whose metes and bounds are unclear. As the phrase is simply intended use language and does not actually further limit the claim, the phrase "in order to be processed further" should be deleted from the claim language.

Claims 31-32 are vague and indefinite in that there is no clear and positive prior antecedent basis for the term "poly(hydroxy fatty acid)" in claim 1, upon which these claims are

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recites "a poly(hydroxy fatty acid)". It would be remedial to amend claim 1 to provide a clear and positive prior antecedent basis for the term "poly(hydroxy fatty acid)".

Claim 33 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "case" in claim 10, upon which claim 33 is dependent. It would be remedial to amend the claim to read "each step".

Claim 33 is also vague and indefinite in that the metes and bounds of the phrase "after approximately 12 h and 24 h at approximately 30°C" are unclear. It is unclear as the claim is written as to whether the term "30°C" simply refers to the temperature at the time of addition of the carbon source to the culture media, or refers to the temperature of the culture media for the duration of the incubation or cultivation time. It would be remedial to amend the claim by making clear what exactly is referred to by the duration and temperature limitations recited in the claim (e.g. by spelling out "hours" and by inserting the appropriate term, incubation or cultivation or growth, etc.).

Claims 34-35 are vague and indefinite in that there is no clear and positive prior antecedent basis for the term "cultivation" in claim 1, upon which claims 34-35 are directly dependent. It is unclear whether the step of "cultivation" implies an additional step to the "incubation" step of claim 1, or whether it specifies an additional method step.

Claim 36 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "poly(hydroxy fatty acid) polymer" in claim 1, upon which claim 36 is dependent. Also, the claim is confusing in that it recites a Markush of "one or more monomers" and then recites different combinations of monomers. It would be remedial to amend the claim



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language by inserting the words "combination of" between the words "more" and "monomers" in line two of claim 36.

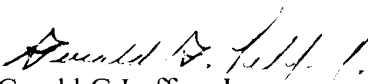
*Conclusion*

The claims are free of the art. No claims are allowed due to 112 1<sup>st</sup> and 2<sup>nd</sup> paragraph issues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Gerald G Leffers Jr.  
Examiner  
Art Unit 1636

Ggl  
March 21, 2003